K083900

FEB 27 2009

510(k) Summary
Erbium Fractional Handpiece

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 82 Cambridge Street
Burlington, MA 01803
Phone: (781) 993-2300
Fax: (781) 993-2330

CONTACT: Sharon Timberlake, MSHS, RAC, CCRA
Director of Regulatory Affairs

DATE PREPARED: February 5, 2009

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: Erbium Fractional Handpiece

COMMON/USUAL NAME: Dermatological Erbium Laser

CLASSIFICATION NAME: Laser surgical instrument for use in general and plastic surgery and in dermatology
(21 CFR § 878.4810)

PRODUCT CODE: GEX

3. PREDICATE DEVICES

Palomar Medical Technologies, Inc.
Palomar Erbium Fractional Handpiece
K071768

Palomar Medical Technologies, Inc.
Palomar Erbium Handpiece
K071152, K063571

Palomar Medical Technologies, Inc.
Lux1540 Fractional Handpiece
K080244

K083900

Reliant Technologies, Inc.
Fraxel III SR Laser System (Fraxel Re:Pair™)
K080915

4. INTENDED USE

The Erbium Fractional Handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.

5. DEVICE DESCRIPTION

The Erbium Fractional Handpiece attaches to the StarLux Pulsed Light and Laser Systems. The complete system consists of a cart, system console, chiller, a footswitch, and a handpiece.

6. PERFORMANCE DATA

The specifications and indications for use of the Erbium Fractional are substantially equivalent to its predicate devices based on the data provided in premarket notification. Thus, it does not result in additional safety or effectiveness information.

7. SUBSTANTIAL EQUIVALENCE

The Erbium Fractional Handpiece is substantially equivalent to its predicate devices when used according to its intended use. The information that is provided in this premarket notification demonstrates that the Erbium Fractional Handpiece also shares the same technological characteristics, mechanism of action, intended use and physical properties to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Palomar Medical Technologies, Inc.
% Sharon Timberlake, MSHS, RAC, CCRA
82 Cambridge Street
Burlington, Massachusetts

FEB 27 2009

Re: K083900
Trade/Device Name: Erbium Fractional Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 24, 2008
Received: December 29, 2009

Dear Ms. Timberlake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083900

Device Name: Erbium Fractional Handpiece

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083900